REMARKS/ARGUMENTS

35 USC § 112, second paragraph

Claims 1-6, and 17-18 were rejected under 35 USC § 112, second paragraph, as being indefinite for use of the term "an information". It appears as though the office understood the term "information" as being implicit in the binding to glypican-1 (page 5 of present action, end of first paragraph). However, such understanding is not what was intended to be covered. The term information" was intended to be understood as a printed (or otherwise displayed) information that allows to draw a specific conclusion to the event of binding to a tissue. To even more clearly delineate the claim, the applicant amended claims 1 and 6 to now recite "an instruction".

35 USC § 102 (b)

Claims 1-6 were rejected under 35 USC § 102(b) as being anticipated by Birembaut et al. (Journal of Pathology 145: 283-296 (1985)). The applicant disagrees, especially in view of the amendments herein. The examiner stated in the office action on page 4 that "...heparin sulphate proteoglycan...[would have been]...known [in the art] as glypican-1...". Such statement is factually incorrect.

The term "heparan sulphate proteoglycan" denotes a class of diverse molecules as can be taken from OMIM entry 600395: "...Cell surface heparan sulfate proteoglycans are composed of a membrane-associated protein core substituted with ***a variable number of heparan sulfate chains***. Two ***different cell surface heparan sulfate proteoglycan families can be distinguished***: (1) the syndecan-like integral membrane proteoglycans (SLIPS), with a core protein spanning the cytoplasmic membrane, and (2) the glypican-related integral membrane proteoglycans (GRIPS), with a core protein anchored to the cytoplasmic membrane via a glycosyl phosphatidylinositol. Clearly, the office assertion that heparan sulphate proteoglycan would be glypican-1 is untenable and the rejection should be withdrawn for at least this reason.

Moreover, it should be noted that Birembaut et al. teach loss of regular arrangement of various basement membrane components as being indicative of malignancies (see page 294, right column, first two sentences in last paragraph). Thus, ***Birembaut are concerned with***

heparan sulphate proteoglycan arrangement, but not presence or absence. Remarkably, various heparan sulphate proteoglycans are reported to be present in healthy and malignant tissue, which is entirely inconsistent with the presently claimed subject matter (but consistent with the presence of other, non-glypican-1 heparan sulphate proteoglycan species).

Claims 1-6 were rejected under 35 USC § 102(b) as being anticipated by Karthikeyan et al. as evidenced by Kleeff. It is undisputed by the applicant that Karthikeyan teaches rat anti-glypican-1 antibodies and that Kleef teaches that the rat anti-glypican-1 antibody also recognizes human glypican-1. However, the instant claims include two substantial elements that cannot be ignored.

First, as amended herein, the ***claim 1 expressly requires an instruction as part of the kit*** that provides ***information that binding of the binding molecule to a cell is indicative of a human cancer cell that overexpresses glypican-1***. Similarly, amended ***claim 5 expressly requires an instruction as part of the kit*** that provides ***information that binding of the binding molecule to the cancer cells slows growth of the cancer cells that overexpress glypican-1***. Such instruction is neither literally nor inherently present in the cited references. Such instruction has historically been recognized by the USPTO as a structural component of a kit and should not be considered intended use (numerous patents have issued with such instructions, see e.g., U.S. Pat. No. 6,602,410, 6,734,212, 7,141,377, 7,097,968, and 5,582,985).

Second, the office failed to provide any arguments in reply to the applicant's position that ***reliance on the preamble during prosecution would transform the preamble into a claim limitation***. Indeed, the office merely stated without any reasoning that the preamble would read on intended use and that the kit language would do so as well. Such statement, however, was not responsive to the legal authority cited. It should be noted that the applicant's reliance is well recognized by the courts (see e.g., , *Catalina Mktg. Int'l v. Coolsavings.com, Inc.*, 289 F.3d at 808-09, 62 USPQ2d at 1785; *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165-66 (Fed. Cir. 1999); and *Jansen v. Rexall Sundown, Inc.*, 342 F.3d 1329, 1333, 68 USPQ2d 1154, 1158 (Fed. Cir. 2003)). ***Proper arguments as to why such legal precedent would not apply in the instant case is respectfully requested.***

Consequently, as the cited references fail to teach the claimed subject matter, the office's anticipation rejection of claims 1-16 should be withdrawn.

Claims 1-6 were rejected under 35 USC § 102(b) as being anticipated by Ivins et al. as evidenced by Kleeff. Once more, it is undisputed by the applicant that Ivins teaches rat anti-glypican-1 antibodies and that Kleef teaches that the rat anti-glypican-1 antibody also recognizes human glypican-1. However, substantial elements present in the claims have been ignored, and with respect to the instruction elements (claim 1: "…instruction that provides information that binding of the binding molecule to a cell is indicative of a human cancer cell that overexpresses glypican-1…"; claim 5: "…instruction that provides information that binding of the binding molecule to the cancer cells slows growth of the cancer cells that overexpress glypican-1…") and the preamble limitations (claim 1: "…diagnostic kit for detection of a human cancer cell that expresses glypican-1…"; claim 5: "…therapeutic kit comprising a therapeutic agent at a concentration effective to slow growth of human cancer cells identified to express glypican-1…"), the same arguments as provided above apply as Ivins and Kleeff fail to teach these specific elements.

Claims 1-6 were rejected under 35 USC § 102(b) as being anticipated by Liang et al. as evidenced by Kleeff. Again, it is undisputed by the applicant that Liang teaches rat anti-glypican-1 antibodies and that Kleef teaches that the rat anti-glypican-1 antibody also recognize human glypican-1.

However, once more substantial elements present in the claims have been ignored. First, the amended claims require an instruction (claim 1: "…instruction that provides information that binding of the binding molecule to a cell is indicative of a human cancer cell that overexpresses glypican-1…"; claim 5: "…instruction that provides information that binding of the binding molecule to the cancer cells slows growth of the cancer cells that overexpress glypican-1…") and the preamble further expressly recites specific limitations not met by the references (claim 1: "…diagnostic kit for detection of a human cancer cell that expresses glypican-1…"; claim 5: "…therapeutic kit comprising a therapeutic agent at a concentration effective to slow growth of human cancer cells identified to express glypican-1…"). Once more, the same arguments as provided above apply as Liang and Kleeff fail to teach these specific elements.

Claims 1-6 were rejected under 35 USC § 102(b) as being anticipated by Litwack et al. as evidenced by Kleeff. It is once more undisputed by the applicant that Litwack teaches rat anti-glypican-1 antibodies and that Kleef teaches that the rat anti-glypican-1 antibody also recognizes human glypican-1.

However substantial elements present in the claims have again been ignored as the claims as amended require an instruction (claim 1: "...instruction that provides information that binding of the binding molecule to a cell is indicative of a human cancer cell that overexpresses glypican-1..."; claim 5: "...instruction that provides information that binding of the binding molecule to the cancer cells slows growth of the cancer cells that overexpress glypican-1..."). The preamble further expressly recites specific limitations not met by the references (claim 1: "...diagnostic kit for detection of a human cancer cell that expresses glypican-1..."; claim 5: "...therapeutic kit comprising a therapeutic agent at a concentration effective to slow growth of human cancer cells identified to express glypican-1..."). Again, the same arguments as provided above apply as Litwack and Kleeff fail to teach these specific elements.

Claims 1-6 were rejected under 35 USC § 102(b) as being anticipated by Liu et al. as evidenced by Kleeff. Once more, it is undisputed by the applicant that Liu teaches rat anti-glypican-1 antibodies and that Kleef teaches that the rat anti-glypican-1 antibody also recognizes human glypican-1. However, substantial elements present in the claims have been ignored, and with respect to the instruction elements (claim 1: "...instruction that provides information that binding of the binding molecule to a cell is indicative of a human cancer cell that overexpresses glypican-1..."; claim 5: "...instruction that provides information that binding of the binding molecule to the cancer cells slows growth of the cancer cells that overexpress glypican-1...") and the preamble limitations (claim 1: "...diagnostic kit for detection of a human cancer cell that expresses glypican-1..."; claim 5: "...therapeutic kit comprising a therapeutic agent at a concentration effective to slow growth of human cancer cells identified to express glypican-1..."), the same arguments as provided above apply as Liu and Kleeff fail to teach these specific elements.

35 USC § 103

Claims 1-6, 17 and 18 were rejected under 35 USC § 103 as being obvious over (1) Karthikeyan et al. as evidenced by Kleef in view Birembaut et al., (2) Ivins et al. as evidenced by Kleef in view Birembaut et al., (3) Liang et al. as evidenced by Kleef in view Birembaut et al., (4) Litwack et al. as evidenced by Kleef in view Birembaut et al., and (5) Liu et al. as evidenced by Kleef in view Birembaut et al., The applicant respectfully disagrees, especially in view of the amendments herein.

With respect to the combination of Karthikeyan et al. and Kleef, Ivins et al. and Kleef, , Liang et al. and Kleef, Litwack et al. and Kleef, and Liu et al. and Kleef, , the same arguments as provided in the respective sections above apply. Furthermore, with respect to Birembaut's teaching of HSP components, the applicant refers to the fact that Birembaut et al. teach presence of HSP in healthy cells, and as such teaches against the claimed subject matter. Thus, Birembaut et al. fail to remedy such defects, and the combination of the cited references does not render the claims obvious.

REQUEST FOR ALLOWANCE

Claims 1-6 and 17-18 are pending in this application. The applicant requests allowance of all pending claims.

Respectfully submitted,

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